



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2018-0604; FRL-9986-45]

### Draft TSCA Risk Evaluation for Colour Index (C. I.) Pigment Violet 29 (PV29); Notice of Availability

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA is announcing the availability of and seeking public comment on the draft Risk Evaluation for Colour Index (C. I.) Pigment Violet 29 (PV29) and associated documents developed under EPA's existing chemical substance process under the Toxic Substances Control Act (TSCA). The purpose of the risk evaluation is to determine whether a chemical substance presents an unreasonable risk to health or the environment under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. EPA is also submitting these same documents to the TSCA Science Advisory Committee on Chemicals (SACC) which will peer review the draft risk evaluation, and EPA will provide the peer review meeting details in a separate **Federal Register** notice. All comments submitted on the draft risk evaluation in response to this Notice of Availability will be provided to the TSCA SACC peer review panel, which will have the opportunity to consider the comments during its discussions. In addition, the subsequent **Federal Register** notice providing details on the peer review meeting will explain the process for submitting information and views to the peer review panel. EPA will consider the public comments on the draft risk evaluation submitted in response to this Notice of Availability, along with peer reviewer comments and recommendations, to finalize the risk evaluation.

**DATES:** Comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** Submit your written comments, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0604, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPPT Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey Dawson, Office of Pollution Prevention and Toxics (7403M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-0331; email address: [dawson.jeffrey@epa.gov](mailto:dawson.jeffrey@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this action apply to me?*

This action is directed to the public in general. This action may be of interest to persons who are interested in risk evaluations of existing chemical substances under the Toxic

Substances Control Act (TSCA). Since other entities may also be interested in this draft risk evaluation, the Agency has not attempted to describe all the entities that may be interested in this action.

*B. What action is the agency taking?*

EPA is announcing the availability of and seeking public comment on the draft Risk Evaluation for Colour Index (C. I.) Pigment Violet 29 (PV29) and associated documents, which is available at the docket identified by ID No. EPA-HQ-OPPT-2018-0604 at <http://www.regulations.gov>. EPA is providing 60 days for public comment on all aspects of this draft risk evaluation, including any conclusions, findings, determinations, and the submission of any additional information that might be relevant to the science underlying the risk evaluation and the outcome of the systematic review associated with C.I. Pigment Violet 29. This 60-day comment period on the draft risk evaluation satisfies TSCA section 6(b)(4)(H), which requires EPA to “provide no less than 30 days public notice and an opportunity for comment on a draft risk evaluation prior to publishing a final risk evaluation.”

In addition to any new comments on the draft risk evaluation, the public should resubmit or clearly identify at this time any previously filed comments, modified as appropriate, that are relevant to this risk evaluation and that the submitter feels have not been addressed. EPA does not intend to further respond to comments submitted prior to the release of this draft risk evaluation.

All comments on the draft risk evaluation in response to this Notice of Availability, and all information and views submitted to the peer review panel as directed in the subsequent **Federal Register** notice announcing the TSCA SACC panel meeting, are being directed to the same docket, identified by docket ID No. EPA-HQ-OPPT-2018-0604 at

<http://www.regulations.gov>. As such, comments submitted or resubmitted during this 60-day period will be provided to the TSCA SACC for consideration during their peer review.

*C. What is the Agency's authority for taking this action?*

TSCA section 6, 15 U.S.C. 2605, requires EPA to conduct risk evaluations to “determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use.” 15 U.S.C. 2605(b)(4)(A). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that direct which chemical substances must undergo evaluation, the development of criteria for manufacturer-requested evaluations, the minimum components of an Agency risk evaluation, and the timelines for public comment and completion of the risk evaluation. The law also requires that EPA operate in a manner that is consistent with the best available science and make decisions based on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i).

The statute identifies the minimum components EPA must include in all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation to be conducted, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. 15 U.S.C 2605(b)(4)(D). The statute further provides that each risk evaluation must also: (1) Integrate and assess available information on hazards and exposure for the conditions of use of the chemical substance, including information on specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations; (2) describe

whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposure. 15 U.S.C. 2605(b)(4)(F)(i), and (iii)-(v). The risk evaluation must not consider costs or other non-risk factors. 15 U.S.C. 2605(b)(4)(F)(ii).

The statute requires that the risk evaluation process last no longer than three years, with a possible additional six-month extension. 15 U.S.C. 2605(b)(4)(G). The statute also requires that the Agency allow for no less than a 30-day public comment period on the draft risk evaluation, prior to publishing a final risk evaluation. 15 U.S.C. 2605(b)(4)(H).

*D. What should I consider as I prepare my comments for EPA?*

1. *Submitting CBI.* Do not submit CBI information to EPA through [regulations.gov](https://www.regulations.gov) or via email. If your comments contain any information that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting your comments.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

## **II. Background**

*A. What is EPA's risk evaluation process for existing chemicals under TSCA?*

The risk evaluation process is the second step in EPA's existing chemical process under TSCA, following prioritization and before risk management. The purpose of risk evaluation is to determine whether a chemical substance presents an unreasonable risk to health or the environment, under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. As part of this process, EPA must evaluate both hazard

and exposure, not consider costs or other non-risk factors, use scientific information and approaches in a manner that is consistent with the requirements in TSCA for the best available science, and ensure decisions are based on the weight-of-scientific-evidence.

The specific risk evaluation process that EPA has established by rule to implement the statutory process is set out in 40 CFR part 702 and summarized on our website at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca>. As explained in the preamble to EPA's procedural final rule (82 FR 33726, July 20, 2017) (FRL-9964-38), the specific regulatory process set out in 40 CFR part 702 will be followed for the first ten chemical substances undergoing risk evaluation to the maximum extent practicable.

#### *B. What is Pigment Violet 29?*

Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f] diisoquinoline-1,3,8,10(2H,9H)-tetrone) (pigment violet 29) is a perylene derivative used to color materials and as an intermediate for other perylene pigments. The pigment is utilized as an intermediate to create or adjust the color of other pigments, as well as in commercial paints, coatings, plastics, and rubber products. C.I. Pigment Violet 29 is an organic pigment that has a low solubility, low volatility, is expected to be highly persistent and has low bioaccumulation potential in fish and other animals.

Information about the problem formulation and scope phases of the risk evaluation for this chemical is available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-pigment-violet-29-anthra219-def6510>.

#### *C. Purpose of the TSCA SACC*

The TSCA SACC was established by EPA to support activities under TSCA, 15 U.S.C. 2601 *et seq.*, the Pollution Prevention Act (PPA), 42 U.S.C. 13101 *et seq.*, and other applicable

statutes. The TSCA SACC provides expert independent scientific advice and recommendations to the EPA on the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated under TSCA. Given the SACC's expertise, EPA is submitting the draft risk evaluation and related documents to the TSCA SACC for peer review and scheduling a public meeting for the panel's discussion of those materials. Consistent with EPA's peer review policy and requirements associated with the Federal Advisory Committee Act (FACA), 5 U.S.C Appendix 2 *et seq.*, EPA will announce the TSCA SACC public meeting and provide related details about that meeting in a future **Federal Register** notice.

**Authority:** 15 U.S.C. 2601 *et seq.*

Dated: November 9, 2018.

**Nancy B. Beck,**

*Deputy Assistant Administrator,*

*Office of Chemical Safety and Pollution Prevention.*

[FR Doc. 2018-24972 Filed: 11/14/2018 8:45 am; Publication Date: 11/15/2018]